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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/890,335	CEVC ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,38,40-43,45-66 and 68-84* is/are pending in the application.

4a) Of the above claim(s) *46,49,51-54,56,57,61 and 68-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37,38,40-43,45,47,48,50,55,58-60,62-66 and 80-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/17/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/27/2009 has been entered.

The amendment and remarks, filed 5/27/2009 and 7/14/2009, are acknowledged. Claims 37, 46, 49, 51-54, 56-58, 61, 64, 68-70, 72-73, and 75-79 are amended. New claims 80-84 are added. Claims 37-38, 40-43, 45-66, and 68-84 are pending. Claims 46, 49, 51-54, 56-57, 61, and 68-79 are withdrawn as being drawn to non-elected inventions. Claims 37-38, 40-43, 45, 47-48, 50, 55, 58-60, 62-66, and 80-84 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed on 7/17/2009 has been considered. An initialed copy is enclosed. Document UC2 has not been considered because no English language translation has been provided.

Objections Withdrawn

The objection to claim 64 because the claim refers to the units "mg/cm2," is withdrawn in light of applicant's amendment thereto.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37, 38, 40-41, 58-59, 65 and newly submitted claims 80-82 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Paul *et al.* (Vaccine Res., 4:145-164, 1995, IDS filed 12/30/2003), for the reasons set forth in the previous office action in the rejection of claims 37, 38, 40-41, 58-59, and 65.

Applicant argues:

1. That the term "a chemical irritant" has been deleted from claim 37 and the claim has been amended to read "a fragment or a derivative of a chemical irritant." Applicant asserts that claim 37 is novel.

Applicant's arguments have been fully considered and deemed non-persuasive.

As discussed below, the composition of Paul contains triethanolamine which is a derivative of an irritant (ammonia).

As outlined previously, the instant claims are drawn to a transdermal antigenic composition, comprising: (a) a transdermal carrier comprising a penetrant suspended or dispersed in an aqueous solvent, the penetrant in the form of a minute fluid droplet surrounded by a coating of one or more layers of at least 2 substances that differ by at least a factor of 10 in solubility, the substances forming homoaggregates of one substance and/or heteroaggregates of the at least 2 substances, the average diameter of homoaggregates of the more soluble substance, or the average diameter of the heteroaggregates of the at least 2 substances, being smaller than the average diameter of homoaggregates of the less soluble substance, and/or the more soluble substance solubilizing the droplet and the content of the more soluble substance being up to 99 mol-% of the concentration required to solubilize the droplet or corresponding to up to 99 mol-% of the saturating concentration in an unsolubilized droplet, whichever is higher, and/or wherein the elastic deformation energy of the droplet surrounded by the coating is at least 5 times lower than the elastic deformation energy of red blood cells or of a phospholipid bilayer having fluid aliphatic chains; (b) a compound which specifically has or induces cytokine or anti- cytokine activity; (c) an antigen or mixture thereof and/or an allergen or mixture thereof; and (d) an extract or a compound from a pathogen, a fragment or a derivative of a chemical irritant, or compound isolated from a pathogen.

Paul *et al.* disclose a transdermal carrier (see page 146, paragraph 3) known as a transfersome (comprising ethanolic soybean phosphatidylcholine, sodium cholate, and lipid A,

which induces cytokine activity) which is associated with an antigen (purified BSA, which is an allergen) (see page 148, Transfersomes preparation). Sodium cholate is a surfactant and therefore an irritant. Additionally, the composition contains triethanolamine, which is a derivative of an irritant (see page 148, Transfersomes preparation). Regarding claim 38, the transfersomes of Paul include sodium cholate, which is the conjugate base of cholic acid. In all acid-base reactions, the acid will react with a base to form the conjugate base and vice versa, switching ionization states. The dissociation constant of sodium cholate is such that, in the transfersome composition of Paul, there would be two ionization states of sodium cholate. Regarding claim 40, phosphatidylcholine is a polar lipid and sodium cholate is a surfactant. Said transfersomes have the same composition as the claimed vaccine carrier and would thus necessarily have the same physical and immunological properties as the claimed vaccine transfersomes. Regarding claims 82 and 84, the intended use of providing "a protective or tolerogenic immune response" does not distinguish over the prior art because it appears that the prior art structure is capable of performing the intended use. Since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37-38, 40-45, 47-48, 50, 55, 58-60, 62-66 and newly submitted claims 80-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenn *et al.* (PCT Publication, WO 98/20734, 1998) in view of Paul *et al.* (Vaccine Res., 4:145-164, 1995, IDS filed 12/30/2003 for the reasons set forth in the rejection of claims 37-38, 40-45, 47-48, 50, 55, 58-60, and 62-66 in the previous office action.

Applicant argues:

1. That Glenn's results show that tetanus toxin generated low levels of antibodies that were far below the levels generated by the other toxins tested. Applicant asserts that, despite a few statements to the contrary, Glenn teaches one skilled in the art that tetanus toxin does not appear to be a good candidate for transdermal delivery to provide a protective immune response, based on results showing a weak immune response. Applicant also argues that, since Glenn showed a survival rate of 61% in a cholera toxin challenge, with antibody titers that were much higher than those induced by tetanus toxin, one of skill in the art would find that Glenn teaches that tetanus toxin is not a good candidate for noninvasive transdermal immunization. Thus, Glenn teaches away from using tetanus toxin in a transdermal vaccine.

2. That Glenn teaches away from a combination of tetanus toxin with IL-12 because IL-12 is not a bARE and tetanus toxin is a poor immunogen even with a bARE adjuvant.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, while the IgG levels induced by tetanus toxin were lower than those induced by other toxins, this does not mean that tetanus toxin is unsuitable for transdermal vaccination. Glenn did not provide any challenge studies with tetanus toxin and used ELISA units, which are derived by using a standard curve generated during the test. These results were not converted to international units and thus do not show whether or not protective antibody levels were obtained. Furthermore, the combination of IL-12 and tetanus toxin was not tested. Therefore, one cannot actually make a determination that the disclosed composition of tetanus toxin and IL-12 would be unsuitable for vaccination. However, Glenn does disclose a

transdermal vaccine comprising IL-12 and tetanus toxin. Glenn states "we envision that the transcutaneous immunization system using toxin-based immunogens and adjuvants can achieve anti-toxin levels adequate for protection against these diseases" (page 21, lines 32-35). There is no evidence to show that this is incorrect. In addition, Paul *et al.* found that it is possible to elicit an immune response epicutaneously, only if one knows precisely how and with which tools it must be done. Paul discloses transfersomes, which are capable of doing this. Therefore, one would expect to achieve better results using the transfersomes of Paul than the aqueous solutions of Glenn.

While Glenn may teach that other toxins are more immunogenic in their delivery system than tetanus toxin, this does not constitute a teaching away from the use of tetanus toxin in a transdermal vaccine. First, Glenn discloses a transdermal vaccine comprising tetanus toxin and IL-12 as one of the embodiments of their invention. This could hardly be considered a teaching away from such a vaccine. Furthermore, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). Simply finding that other toxins are more efficacious does not constitute a teaching away from tetanus toxin.

Regarding argument 2, as stated above, a finding that tetanus toxin is a poorer immunogen than other toxins does not imply that one would not use it. In addition, Glenn did not test IL-12 and thus did not show or imply that it would be insufficient as an adjuvant with tetanus toxin.

Regarding arguments 1 and 2, applicant's arguments are directed to why one would not choose tetanus toxin to modify the transdermal composition of Paul. However, this is not the basis for the rejection. The rejection is based on the fact that it would be obvious to modify the transdermal vaccine of Glenn by using the transdermal carrier of Paul. Glenn discloses a transdermal vaccine comprising tetanus toxin and IL-12. This is straightforward and clearly disclosed. Whether or not one would chose tetanus toxin for use in a transdermal vaccine is not relevant, as such a vaccine was clearly disclosed by Glenn. This vaccine could be made better by using the transdermal carrier disclosed by Paul.

More importantly, applicant's arguments are all directed toward why one would not use tetanus toxin and IL-12 in a transdermal vaccine. First, only claims 82-84 are drawn to vaccines. Second, there is no claim currently pending that is limited to these components. These are the components applicant has elected for examination; however, none of the claims are so limited. Applicant has indicated the suitability of various other toxins and adjuvants disclosed by Glenn for use in transdermal vaccines and these toxins and adjuvants are encompassed by the instant claims.

As outlined previously, the instant claims are drawn to a transdermal antigenic composition, comprising: (a) a transdermal carrier comprising a penetrant suspended or dispersed in an aqueous solvent, the penetrant in the form of a minute fluid droplet surrounded by a coating of one or more layers of at least 2 substances that differ by at least a factor of 10 in solubility, the substances forming homoaggregates of one substance and/or heteroaggregates of the at least 2 substances, the average diameter of homoaggregates of the more soluble substance, or the average diameter of the heteroaggregates of the at least 2 substances, being smaller than the average diameter of homoaggregates of the less soluble substance, and/or the more soluble substance solubilizing the droplet and the content of the more soluble substance being up to 99 mol-% of the concentration required to solubilize the droplet or corresponding to up to 99 mol-% of the saturating concentration in an unsolubilized droplet, whichever is higher, and/or wherein the elastic deformation energy of the droplet surrounded by the coating is at least 5 times lower than the elastic deformation energy of red blood cells or of a phospholipid bilayer having fluid aliphatic chains; (b) a compound which specifically has or induces cytokine or anti- cytokine activity; (c) an antigen or mixture thereof and/or an allergen or mixture thereof; and (d) an extract or a compound from a pathogen, a fragment or a derivative of a chemical irritant, or compound isolated from a pathogen

Glenn *et al.* disclose a transdermal vaccine that contains tetanus toxoid and interleukin-12 (see abstract; page 16, lines 15-17; and page 18, lines 15-30). Glenn *et al.* state that the antigens used in the vaccine can be purified (see paragraph bridging pages 15-16).

Glenn *et al.* differs from the instant invention in that the transdermal vaccine does not comprise a carrier wherein the substances forming homoaggregates of one substance and/or heteroaggregates of the at least 2 substances, the average diameter of homoaggregates of the

more soluble substance, or the average diameter of the heteroaggregates of the at least 2 substances, being smaller than the average diameter of homoaggregates of the less soluble substance, and/or the more soluble substance solubilizing the droplet and the content of the more soluble substance being up to 99 mol-% of the concentration required to solubilize the droplet or corresponding to up to 99 mol-% of the saturating concentration in an unsolubilized droplet, whichever is higher, and/or wherein the elastic deformation energy of the droplet surrounded by the coating is at least 5 times lower than the elastic deformation energy of red blood cells or of a phospholipid bilayer having fluid aliphatic chains.

Paul *et al.* disclose a transdermal carrier (see page 146, paragraph 3) known as a transfersome (comprising ethanolic soybean phosphatidylcholine, sodium cholate, and lipid A, which induces cytokine activity) which is associated with an antigen (purified BSA, which is an allergen) (see page 148, Transfersomes preparation). Sodium cholate is a surfactant and therefore an irritant. Additionally, the composition contains triethanolamine, which is a derivative of an irritant (see page 148, Transfersomes preparation). Said transfersomes have the same composition as the claimed vaccine carrier and would thus necessarily have the same physical and immunological properties as the claimed vaccine transfersomes. Additionally, Paul *et al.* disclose that transdermal immunization using large protein molecules can be accomplished using said transfersomes, and that, if properly optimized, a transdermal drug transfer efficacy of > 90% can be achieved (see page 162, paragraphs 7-8). Paul *et al.* further disclose that vaccination can be accomplished using full size proteins across the intact skin (see page 146, paragraph 3).

It would have been obvious to one of ordinary skill in the art to use the transdermal carrier (transfersomes) of Paul *et al.* in the vaccine of Glenn *et al.* in order to take advantage of the high drug transfer efficacy of transfersomes, as disclosed by Paul *et al.* One would have had a reasonable expectation of success because Paul *et al.* disclose that their transfersomes are capable of delivering full size proteins across the skin in a vaccination. Regarding claim 38, the transfersomes of Paul include sodium cholate, which is the conjugate base of cholic acid. In all acid-base reactions, the acid will react with a base to form the conjugate base and vice versa, switching ionization states. The dissociation constant of sodium cholate is such that, in the transfersome composition of Paul, there would be two ionization states of sodium cholate.

Regarding claim 40, phosphatidylcholine is a polar lipid and sodium cholate is a surfactant. Said transfersomes have the same composition as the claimed vaccine carrier and would thus necessarily have the same physical and immunological properties as the claimed vaccine transfersomes. Regarding claims 41-43, 50, 55, 60, and 62-64, these claims are merely optimized ranges for materials in the vaccine. Paul *et al.* disclose that the vaccine should be properly optimized to achieve efficacy. Further, according to MPEP 2144.05, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Regarding claim 66, the vaccine disclosed by the prior art are packaged in some form, thus anticipating the limitation of a kit containing said vaccine in a packaged form. Therefore, as the vaccine disclosed by the prior art contains a dose of antigen, the prior art anticipates this limitation.

New Claim Rejections

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 82-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions to provide a protective immune response against tetanus comprising tetanus toxoid as the antigen, does not reasonably provide enablement for protective immune responses against any given disease comprising any given antigen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary.

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of

knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims are drawn to a transdermal vaccine that comprises a transdermal carrier, a compound which specifically has or induces cytokine or anti-cytokine activity, and any antigen or allergen or mixture of antigens or allergens. The claim encompasses all antigens and allergens and all diseases.

Guidance of the specification/The existence of working examples: The specification discloses, in the examples, challenge experiments using the claimed vaccine wherein the antigen is tetanus toxoid. The specification is devoid of any teaching that any antigen other than the tetanus toxoid provides an effective vaccine against any disease when administered transdermally. To be a prophylactic composition, the composition must elicit protective immunity, demonstrable by pathogen challenge experiments in a reasonable model system. The skilled artisan would clearly realize the critical deficiency of this specification with respect to vaccines. There is absolutely no demonstration of protective immunity upon the transdermal administration in any animal model of disease by all of the antigens encompassed by the claims. Therefore it is not clear which of the claimed antigens are capable of generating a protective immune response against a given disease, when administered transdermally.

State of the art: Although many investigators have tried to develop vaccines based on specific antigens, it is well understood that the ability of an antigen to stimulate antibody production does not necessarily correlate with the ability of the antigen to stimulate an immune response capable of protecting an animal from infection (Chandrashekar *et al.*, US Patent

6,248,329, col. 1, lines 35-41). It is well recognized in the vaccine art, that it is unclear whether an antigen derived from a pathogen will elicit protective immunity. Ellis (Chapter 29 of Vaccines, Plistkin, *et al.* (eds) WB Saunders, Philadelphia, 1998, especially p. 571, paragraph 2) exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies... and thus protect the host against attack by the pathogen."

The specification fails to teach that any of the claimed antigens other than the tetanus toxoid can produce a protective response in the host, as is requisite of a vaccine composition. In view of the lack of support in the art and specification for an effective vaccine comprising the claimed proteins, it would require undue experimentation on the part of the skilled artisan to make and use the vaccine as claimed; therefore the full scope of the claims are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 60 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 60 recites the limitation "the irritant" in line 2. There is insufficient antecedent basis for this limitation in the claim. The parent claim does not require an "irritant," instead requiring a fragment or derivative of an irritant. Such a derivative or fragment does not necessarily have to be an irritant.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645